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# Natural health products — Substantiating the claims

*CPJ* IS TO BE COMMENDED FOR INVITING ITS READERS TO WEIGH IN ON THE debate surrounding the natural health products (NHP) regulations.[1,2] Consumer Health Products Canada (formerly Nonprescription Drug Manufacturers Association of Canada) has been actively working toward having appropriate NHP regulations implemented for more than 20 years. Yet, more than a decade after the Minister of Health accepted the Standing Committee on Health's 53 recommendations regarding the safety, quality and efficacy of NHPs[3] and almost 6 years after the resulting NHP regulations were passed, the controversy around this issue is unrelenting.

NHPs account for at least a third of CHP Canada members' total sales (which, in turn, account for the vast majority of all consumer health product sales in Canada). They are a key part of our business. Given the strong and growing role they play in patient self-care, NHPs are also an important part of pharmacy practice. For both pharmacy and industry, the importance of the NHP regulations stems directly from the importance of NHPs themselves to our patients and customers.

While there are many opinions about the regulation of NHPs, there can only be one set of facts. In the November/December issue of *CPJ*, a representative of the Canadian Health Food Association claimed that Canadians have already lost access to a broad range of NHPs and that the situation is about to get much worse.[2] He also alleged that the government is evaluating the efficacy of NHPs as if they were drugs and that the vast majority of license rejections are because of the absence of "double-blind human clinical studies." These claims simply don't line up with the facts.

If Canadians are losing access to NHPs, it isn't reflected in the growing presence of these products in pharmacies, food stores and mass merchandisers over the past decade, or in the booming health food/supplement store sector. When the *CPJ* editorial was being written, just shy of 16,000 NHP licenses representing almost 21,000 products had been granted. Now, just 7 weeks later, the number of NHP licenses has jumped to over 18,000, exceeding the number of consumer health products with DINs (OTCs). That's enough to fill an entire food/drug superstore with NHPs and nothing else!

Yes, there have been many high-profile cases of NHPs being removed from the market due to *safety* concerns (often imported products containing undeclared prescription drugs or contaminants), but CHP Canada has repeatedly asked to see examples of the kinds of products that are in peril of disappearing because of *efficacy* standards. Time and again, the examples we see are products containing ingredients that *have* been approved under these regulations. Almost invariably, the real issue is the *claims* that some manufacturers want to make for such products, with little supporting evidence. Sure, some manufacturers may be losing access to unsupported claims, but consumer access to the NHP ingredients themselves appears very robust indeed.

The allegation that Health Canada is evaluating NHPs as though they were drugs — so-called "pharmaceutical creep" — is absolutely false. The standards of evidence for NHPs could

**TABLE 1 Levels of evidence permitted under NHP regulations[4]**

| Levels of evidence | Type of evidence from human studies |
|---|---|
| I | Well-designed systematic reviews and meta-analyses of randomized controlled trials or other clinical trials, or at least one well-designed randomized controlled trial (preferably multicentred) |
| II | Well-designed clinical trials without randomization and/or control groups |
| III | Well-designed descriptive and observational studies, such as correlational studies, cohort studies and case-control studies |
| IV | Peer-reviewed published articles, conclusions of other reputable regulatory agencies or previous marketing experience, expert opinion reports, referenced textbooks, website (if the information is peer-reviewed and there is a hardcover version of the site, e.g., Natural Medicines Comprehensive Database) |
| V | References of a traditional use, pharmacopoeias |

not be more different than they already are from those used for conventional nonprescription drugs. Thousands of NHP product licenses have been granted for traditional claims based on traditional pharmacopoeias and references that do not require any scientific support at all. For non-traditional claims, Health Canada permits a variety of evidence that goes far beyond "double-blind human clinical studies" (see Table 1). The level of evidence required is tied to the strength of the claim, with therapeutic claims generally requiring Level I or II evidence and lesser claims (risk reduction or structure-function claims) allowed on the basis of Level III or IV evidence.

As the time arrives for Health Canada to fulfill the Standing Committee's recommendations on enforcement of the regulations, Parliament is being bombarded with yet another campaign of letters, postcards and e-mails announcing the impending doom of the NHP sector. These campaigns, driven increasingly by the savvy use of social media networks, have been an ongoing feature of the NHP regulatory exercise for more than a decade. Parliamentarians have commented that the volume of mail on this subject exceeds what they have seen on almost any other issue. And yet very little of it is based in fact.

In truth, Health Canada's Natural Health Products Directorate has managed remarkably well in its implementation of the Standing Committee's recommendations. What had been a hodgepodge of inappropriately limiting regulations and widespread grey-zone marketing has shaped up into a system that gives Canadians informed (i.e., properly labelled) access to tens of thousands of safe natural health products. The final step in the process is full regulatory compliance and enforcement. After many years of hard work by all stakeholders, the time for that step has arrived. ■

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## References

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**3.** Standing Committee on Health. Natural health products: a new vision. Ottawa (ON): Public Works and Government Services Canada; 1998. Available: www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=1031528&File=6 (accessed December 7, 2009).

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